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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action SummaryApplication No.
09/232,861Applicant(s)
Knapp et al

Examiner

FOX

Group Art Unit

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--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--**Period for Reply**

-3-

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status Responsive to communication(s) filed on 6/28/00 This action is **FINAL**. Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.**Disposition of Claims** Claim(s) 17-62 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

 Claim(s) 42 and 53-60 is/are allowed. Claim(s) 17-41, 43-52 and 61-62 is/are rejected. Claim(s) _____ is/are objected to. Claim(s) _____ are subject to restriction or election requirement.**Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The proposed drawing correction, filed on _____ is approved disapproved. The drawing(s) filed on _____ is/are objected to by the Examiner. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner.**Priority under 35 U.S.C. § 119 (a)-(d)** Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). All Some* None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) _____. received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s) Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ Interview Summary, PTO-413 Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152 Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____**Office Action Summary**

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Claim 39 remains in error as stated in the last office action.

The corrected oath of 28 June 2000 has been received.

The amendments and Terminal Disclaimers of 28 June 2000 have obviated the obviousness-type double patenting rejections, the rejections under 35 USC 112, second paragraph, the rejection under 35 USC 112, first paragraph that appeared on pages 5-7 of the last office action, and the rejection under 35 USC 102.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 49 (newly submitted) is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to a cruciferin promoter, as stated in the last office action for claim 42.

Claims 17-41, 43-48 and new claims 49-52 and 61-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated in the last office action for claims 17-48.

Claims 17-32, 33 (amended), 34-37, 38 (amended), 39-40, 41 (amended), 43-48 and new claims 50-52 and 61-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over

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Zambryski et al taken with Sengupta-Gopalan et al, as stated in the last office action for claims 17-32, 34-37, 39-40 and 43-48.

Claims 20, 33, 38 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Zambryski et al taken with Sengupta-Gopalan et al as applied to claims 17-41, 43-48, 50-52 and 61-62 above, and further in view of Pedersen et al, as stated in the last office action.

Claims 17-41, 43-48 and new claims 50-52 and 60-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al, as stated in the last office action for claims 17-32, 34-37, 39-40 and 43-48.

Claims 20, 33, 38 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hall et al (U.S. Patent 5,504,200) taken with Sengupta-Gopalan et al as applied to claims 17-41, 43-48, 50-52 and 60-62 above, and further in view of Zambryski et al taken with Pedersen et al, as stated in the last office action.

Claim 42 and new claims 49 and 53-60 are deemed free of the prior art, for the reasons stated in the last office action for claim 42.

Claims 42 and 53-60 are allowed.

Applicants' arguments filed 28 June 2000, insofar as they pertain to the rejections above, have been fully considered but they are not persuasive.

Applicants urge that the enablement rejection with regard to the cruciferin promoter is improper, given the teaching in the specification that Simon et al (1985) identified cruciferin cDNA clones from *Brassica napus*, the identification of cruciferin cDNA clones from radish by

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Laroche-Raynal et al (1986) as evidenced by an Abstract appended to the amendment of 28 June 2000, the ability of Sjodahl et al (1995) to elucidate the fine structure of the *Brassica napus* cruciferin gene promoter directly upstream of the coding region as evidenced by an appended Abstract, the high level of skill in the art, the disclosure in the specification of the identification of promoters from the upstream regions of three other *Brassica* genes, and the ability of Sengupta-Gopalan et al cited by the Examiner to obtain seed-specific promoter function from a directly upstream region of the phaseolin gene.

The Examiner maintains that Laroche-Raynal et al is drawn to a different plant species (for which the instant specification provides no genomic or cDNA clones) and was not cited in the instant specification, while the actual cDNA of Simon et al briefly mentioned in the paragraph bridging pages 62 and 63 was not further elucidated in the specification. Therefore, the instant specification does not provide one skilled in the art the starting materials from which to isolate a *Brassica napus* cruciferin promoter. See *Genentech* cited in the last office action. With regard to Sjodahl et al, see In re Glass, 181 USPQ 31, 34 (CCPA 1974), which teaches that references published after the filing date of an application may not be relied upon for the enablement of the specification.

Applicants urge that the written description rejection is improper, given the failure of a particular promoter to be essential to the claimed method, Example 18 of the "Revised Interim Written Description Guidelines Training Materials" drawn to method claims, and the failure of the case law cited by the Examiner to deal with method claims.

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The Examiner maintains that the instant claims differ from those of Example 18 of the Guidelines. In Example 18, the novelty resided in the transformation of a particularly claimed *single* fungal species, wherein any gene encoding any protein of interest could be employed. Thus, the claim scope was commensurate with what was described in the specification. In the instant situation, claim 49 specifically claims a promoter that was neither obtained nor described by the instant specification. Furthermore, the remaining claims are broadly drawn to any seed-specific or seed-preferential promoter from any of a multitude of plant species, wherein said seed-specific or seed-preferential promoter type is in fact crucial to the claimed invention, while the instant specification only demonstrates the isolation and description of three promoters from the single species of *Brassica napus*. Thus, the instant situation involves a method requiring particular products (promoters) which are essential to the claimed invention, wherein the description of these products in the specification is not commensurate with the claim scope.

With regard to method versus composition claims, the Examiner notes that the Revised Guidelines encourage reliance upon the case law cited by the Examiner, and do not prohibit the application of written description rejections to method claims in general.

Applicants urge that the rejections of the claims under 35 USC 103 over Zambryski et al taken with Sengupta-Gopalan et al are improper, given the failure of either reference to teach or suggest plant transformation with a construct comprising a tissue-specific promoter and a heterologous coding sequence, the failure of Sengupta-Gopalan et al to identify the promoter

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sequence, and the failure of additionally cited references in the second rejection to cure the deficiencies of the prior two references.

The Examiner maintains that the combination of cited references fairly suggests the claimed invention, as stated in the last office action with regard to the excerpted portions of the references, and given the recognition by one of ordinary skill in the art of the value of tissue-specific expression of heterologous structural genes. With respect to Sengupta-Gopalan et al, Applicants' statements regarding the insufficiency of their teachings contradict Applicants' earlier statements on page 21 of the amendment of 28 June 2000, top paragraph. Thus, these two references taken together are not deficient, and the second rejection under 35 USC 103 which specifically addresses soybean as the transformed plant host is also proper.

Furthermore, Applicants' evidence of unexpected results, namely tissue-specific heterologous coding sequence expression under the control of a heterologous tissue-specific promoter, relies upon the use of three different tissue-specific promoters from three different *Brassica napus* genes. In contrast, the claims are broadly drawn to any tissue-specific promoter from any gene from any plant species. See In re Lindner, 173 USPQ 356 (CCPA 1972) and In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Applicants urge that the rejections under 35 USC 103 over Hall et al taken with Sengupta-Gopalan et al are improper, given the failure of Hall et al to teach a heterologous coding sequence, true seed-specificity, or resistance to degradation; the deficiencies of Sengupta-Gopalan

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et al as stated previously; and the failure of the additionally cited references in the second rejection to cure the deficiencies of the prior two references.

The Examiner maintains that the combination of cited references fairly suggests the claimed invention, as stated in the last office action with regard to the excerpted portions of the references, and given the recognition by one of ordinary skill in the art of the value of tissue-specific expression of heterologous structural genes. Furthermore, Hall et al and Sengupta-Gopalan et al teach that the majority of phaseolin expression occurs in the seed, thus fulfilling the requirement of a seed-*preferential* promoter as claimed, and also fulfilling the art-recognized definition of a tissue-“specific” promoter as one which causes gene expression *primarily* in a particular tissue. The Examiner is unaware of a demonstration that Applicants’ three exemplified promoters caused expression exclusively in seed tissue. With regard to product degradation, the Examiner maintains that seed storage proteins are normally degraded upon germination, as they are utilized for the nutrition of the germinating seedling.

With regard to Sengupta-Gopalan et al, the reference is not deficient as discussed above. Thus, these two references taken together are not deficient, and the second rejection under 35 USC 103 which specifically addresses soybean as the transformed plant host is also proper. Furthermore, see *Lindner* and *Grasselli* cited above.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 28, 2000

DAVID T. FOX
PRIMARY EXAMINER
GROUP 1638

David T. Fox